



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville, MD 20857

September 8, 2004

**FILE COPY**

Cristina Neves  
Hikma Farmaceutica (Portugal), Lda  
Estrada Do Rio Da Mo, n 8, 8A – 8B  
Fervenca  
2705-906 Terrugem SNT Portugal

Dear Ms Neves:

Your petition requesting the Food and Drug Administration to determine that betamethasone sodium phosphate has been voluntarily withdrawn from sale for safety or efficacy reasons, was received by this office on 09/07/2004. It was assigned docket number 2004P-0407 and it was filed on 09/07/2004. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Gloria Ortega  
Deputy Director  
Division of Dockets Management  
Office of Management Programs  
Office of Management

2004P-0407

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